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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ROCHE PALO ALTO LLC, GILEAD PALO ALTO, INC. and GILEAD SCIENCES, INC., Plaintiffs, v. LUPIN PHARMACEUTICALS, INC. and LUPIN LTD., Defendants.	Civil Action No. 2:10-cv-03561-ES-CLW REDACTED VERSION

DECLARATION OF R. POLK WAGNER, J.D., IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGEMENT OF INVALIDITY

I, R. Polk Wagner, J.D., declare as follows:

A. Contents of This Declaration

1. The following document contains my analysis of whether the license agreement dated March 27, 1996 between Syntex (USA) Inc., and CV Therapeutics Inc. constitutes an on-sale bar under 35 U.S.C. § 102(b) to the validity of patents in suit related to ranolazine treatment for angina.

B. Qualifications and Experience

2. I am currently a tenured full professor of law at the University of Pennsylvania Law School, where I teach and conduct research on issues related to intellectual property, focusing especially on patent law.

3. I am the author of over twenty articles on patent law and other intellectual property issues, as well as co-author of book, PATENT LAW: CONCEPTS AND INSIGHTS (Foundation Press 2008).

4. I have given several dozens of lectures to audiences in academic settings (for example, Harvard Law School, Stanford Law School, University of Michigan Law School, Columbia Law School, Waseda University [Tokyo, Japan], Shih Hsin University [Taipei, Taiwan], National Law School of India University [Bangalore, India] and many others), national and international industry organizations (for example, BIO, Intellectual Property Owners' Association), national and regional legal organizations (for example, American Intellectual Property Law Association, Association of Corporate Patent Counsel, Houston IP Law Association), federal judges, and the U.S. Patent and Trademark Office.

5. Before joining the University of Pennsylvania Law School Faculty in 2000, I served as a law clerk to Judge Raymond C. Clevenger III of the United States Court of Appeals for the Federal Circuit.

6. I attended Stanford Law School, where I graduated order of the coif, I have a degree in engineering from the University of Michigan, and was the 1994-95 Roger M. Jones Fellow at the London School of Economics in London, UK.

7. I am registered to practice before courts in the state of California and the United States Court of Appeals for the Federal Circuit, and have been admitted to practice before the USPTO since 1997. Additional information related to my background, training, and experience is included in my curriculum vitae, attached hereto as Exhibit A.

8. This declaration is based on my expertise, knowledge and experience. In connection with preparing this declaration I have consulted the declaration of Omri Ben-Shahar in Support of Lupin's Motion; the patents-in-suit; the February 14, 2012 deposition transcript of Andrew Wolf; Plaintiffs' Tabular Listing of All Clinical Studies (GIL-RANEXA00267834-99); and various cases and statutes cited herein.

II

ANALYSIS

9. Section 102(b) of the Patent Act establishes what is known as the "on-sale bar":

> ***35 U.S.C. 102 Conditions for patentability; novelty and loss of right to patent.***
>
> A person shall be entitled to a patent unless - [...] (b) the invention was ... on sale in this country, more than one year prior to the date of the application for patent in the United States ....

10. As consistently interpreted by courts, the on-sale bar has two components: first, there must be a commercial sale (or offer for sale) of the invention; and second, the invention must be "ready for patenting" at the time of the sale (or offer for sale).

11. For purposes of the analysis, here, I will focus only on the first prong of the on-sale bar analysis: whether the March 27, 1996 agreement between Syntex (USA) Inc., and

CV Therapeutics Inc. (hereafter, "the Agreement") is a sale of the sort that 35 U.S.C. § 102(b) contemplates.

12. As I discuss in detail below, I believe there are two independent reasons that the Agreement does not constitute an on-sale bar with respect to the patents at issue in this case. First, the Agreement is best understood as a transfer of a research project, not a commercial sale of the invention itself. And second, even if the Agreement is a commercial sale of the invention, the primary purpose of the transfer is for experimentation, thus precluding application of the on-sale bar. I take each of these analyses in turn below.

A. The Ben-Shahar Declaration Does Not Inform the On-Sale Bar Question

13. Counsel has asked me to review the declaration submitted by Professor Omri Ben-Shahar on behalf of Lupin. I have done so, and in my opinion the declaration does not speak to the question of whether the Agreement triggers the on-sale bar of 35 U.S.C. § 102(b). Professor Ben-Shahar opines that under general principles of contract law, the Agreement is a "sale" or "offer to sell" the ranolazine materials referenced in the Agreement. There are two important reasons the Ben-Shahar Declaration fails here.

14. First, while it is clear that under the patent law the UCC and other contract doctrines provides guidance concerning whether a "commercial offer for sale" under 102(b) has occurred, the Federal Circuit has specifically declined to follow any particular law of contracts, reasoning instead that "[T]he body of case law from which we must draw guidance … is that of the state and federal courts interpreting their individual versions of the UCC. From this body of state law, we will search for the common denominator for assistance in crafting the federal common law of contract that now governs the on-sale bar." *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1048 (Fed. Cir. 2001).

15. Further, this "common law of contract that now governs the on-sale bar" is *a creature of Federal Circuit law alone*: "Because of the importance of having a uniform national rule regarding the on-sale bar, we hold that the question of whether an invention is the subject of a commercial offer for sale is a matter of Federal Circuit law." *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001).

16. Thus, whether the Agreement constitutes a sale or offer to sell ranolazine under the terms of the UCC and/or other jurisdiction is not dispositive of whether the Agreement constitutes a sale or offer to sell ranolazine under 35 U.S.C. § 102(b).

17. Second (and even more importantly), even if Professor Ben-Shahar's declaration answered a more relevant question—whether the Federal Circuit's version of the "common law of contracts that now governs the on-sale bar" points towards the Agreement being a sale or offer to sell ranolazine—the patent law requires courts to analyze the purpose of such transactions in every instance. *Allen Eng'g Corp. v. Bartell Indus., Inc.,* 299 F.3d 1336, 1352-53 (Fed. Cir. 2002).

18. As I note in more detail below, the Agreement, when read as a whole, is plainly intended to transfer a research project to facilitate the development of pharmaceuticals rather than to commercialize the ranolazine that Syntex had on hand at the time of the Agreement. In addition, any "sale" or "offer to sell" ranolazine as part of the Agreement was clearly intended for experimentation. For both of these reasons, the Agreement was not an on sale-bar event under 35 U.S.C. § 102(b), irrespective of Professor Ben-Shahar's analysis under the UCC and California contract law.

B. The Agreement is not a Commercial Sale of the Invention as Required by 35 U.S.C. § 102(b).

19. The purpose of the on-sale bar is two-fold: first, to prevent the extension of the patent grant; and second, to protect the public's access to knowledge. That is, by limiting the time that a patentee may commercially exploit her invention prior to applying for a patent, the on-sale bar prevents patentees from effectively extending the patent grant by delaying their application while commercializing their invention. Similarly, the on-sale bar protects the public by preventing the removal of knowledge (inventions) via patenting—if those inventions have been made commercially available.

20. Importantly, the Agreement here does not implicate either of these two animating concerns of the on-sale bar. The purpose of the Agreement was clearly to transfer the *research project*—the exploration and development of ranolazine as a efficacious pharmaceutical treatment for angina—from Syntex to CVT, not to commercialize any then-extant ranolazine materials. Thus, in my opinion, the Agreement is a transaction between Syntex and CVT which does not trigger the on-sale bar of §

102(b): it does not constitute either a sale or an offer for sale of the invention as required by that section.

21. My assessment is based on my reading of the Agreement as a whole, and in particular the "whereas" clauses, which set forth the purpose of the transaction. [redacted]

22. That is, the Agreement was intended to effectuate a transfer of intellectual property and other know-how from Syntex to CVT, so as to allow the development of pharmaceuticals using the ranolazine compound. This is not the type of transaction contemplated by the on-sale bar of § 102(b). The Agreement did not commercialize ranolazine, certainly not in a way that would allow for an effective extension of the patent grant. Further, the Agreement makes clear that ranolazine materials are not commercially available at the time of the Agreement—indeed the very purpose of the Agreement is to enable the *later* development and (ultimately) the commercialization of ranolazine for treatment of angina.

23. Perhaps even more important than what the whereas clauses say is what they *do not* say. They do not even mention the existence of any ranolazine-related materials, much less suggest that a purpose of the transaction was to sell, offer to sell, or otherwise commercialize those materials. The Agreement's purpose is obviously directed to the transfer of know-how and related patent license rights, not the sale or offer for sale of the invention at issue in this case.

24. This view of the Agreement is further confirmed by understanding that at the time of the Agreement, Federal law prohibited any commercialization of the then-extant ranolazine materials in a way that would implicate the purposes of the on-sale bar.

That is I understand that at the time of agreement, the FDA had not approved ranolazine for treatment of angina; thus ranolazine could not be legally sold or offered for sale in the United States for the trea

[redacted]

25. [redacted]

[redacted]

26. The relevant case law on what constitutes a sale or offer for sale under 35 U.S.C. § 102(b) is in accord with my analysis, and indeed I believe that a finding that the Agreement here triggered the on-sale bar would be an unwarranted and troubling extension of the law.

27. In *Pfaff v Wells*, the Supreme Court established the modern rules of the on-sale bar: "[T]he on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale. An inventor can both understand and control the timing of the first commercial marketing of his invention.... Second, the invention must be ready for patenting." *Pfaff v. Wells*, 525 U.S. 55, 67 (1998).

28. In *Pfaff*, there was no dispute about the commercial offer for sale component of the test: the inventor had accepted a specific purchase order to supply the invention—so the Court did not explore the contours of commercial offer for sale, except to note that sales that were related to experimentation on the invention were not within the scope of § 102(b). *See Pfaff*, 525 U.S. at 64-65.

29. The Federal Circuit, however, has attempted to clarify the scope of the "commercial offer for sale" doctrine. As a general matter, the Federal Circuit has stated that courts should look to the UCC for understanding the nature of a commercial sale or offer for sale under § 102(b). However, this clarification has not been very satisfactory, as the Federal Circuit itself has noted —most prominently in *Linear Tech. Corp. v. Micrel, Inc*, 275 F.3d 1040 (Fed. Cir. 2001). Among other issues, the UCC does not define an offer for sale, so Courts are forced to discern the (federal) common law of contract offers whenever an offer for sale is at issue rather than look to the UCC. Further, the UCC allows for contract formation even if the timing of such formation is unclear—which is obviously problematic from an on-sale bar perspective. Indeed, although it is oft-repeated that UCC principles govern the "commercial offer for sale" component of the on-sale bar, the Federal Circuit in *Linear Tech* concluded that in fact the governing contract law is actually specific to the on-sale bar: "the body of case law from which we must draw guidance ... is that of the state and federal courts interpreting their individual versions of the UCC. From this . . . we will search for the common

denominator . . . in crafting the federal common law of contract that now governs the on-sale bar." *Linear Tech*, 275 F.3d at 1048.

30. This "federal common law of contract that governs the on-sale bar" has some important guideposts. First, following from *Pfaff*, it is clear that a specific purchase order directed to the invention is clearly a "commercial offer for sale." On the other hand, general but widespread promotional activity such as advertising does not trigger the on-sale bar. *See Linear Tech, 275 F.3d at 1048*. Even the sending of samples of the invention to potential customers has been held to fall short of a triggering offer for sale. *See Minnesota Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1308 (Fed. Cir. 2002).

31. Critically for our purposes here, agreements to license patents or potential patents to the invention are not sales or offers under 35 U.S.C. § 102(b). *See Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1267 (Fed. Cir. 1986), cert. denied, 479 U.S. 1030 (1987). Indeed the Federal Circuit in *Mas-Hamilton Group v Legard, Inc.* did not find a commercial offer for sale in a case quite similar to this one, where: (a) physical embodiments of the invention were offered to a potential licensee; (b) money was exchanged; (c) the devices (locks) were for testing or show only; (d) and the overall purpose of the transaction was to transfer either production rights in the invention, or an the exclusive right to market the invention to the government rather than the devices themselves.

32. *Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1217 (Fed. Cir. 1998). And the 9th Circuit (prior to the creation of the Federal Circuit) held that corporate mergers and transactions do not themselves trigger the on-sale bar, even though they may transfer the invention as part of the assets contemplated by the agreement. *See Micro-Magnetic Industries, Inc. v. Advance Automatic Sales* Co., 488 F.2d 771 (9th Cir. 1973).

33. The Federal Circuit itself has made clear that a transaction intended to transfer patent rights or facilitate research and development does not trigger the on-sale bar. In *In re Kollar*, the patent applicant had signed an agreement whose purpose was "conduct[ing] research and development ['R&D'] in the Field [which the Board properly determined includes Kollar's inventive process] ... with a goal to achieving, by the end of 5 R&D years, Celanese approval for a commercial plant in the Field." *In re Kollar*, 286 F.3d 1326, 1330 (Fed. Cir. 2002). The Court ruled that such an agreement did not constitute an on-sale bar. *See id.* at 1333.

34. To be sure, the courts in these cases have noted that a patent license or know-how transfer that is merely a transfer of the invention itself is indeed a commercial offer for sale under 35 U.S.C. § 102(b). For example, in *Minton v. Nat'l Ass'n. of Sec. Dealers, Inc.*, 336 F.3d 1373, 1377 (Fed. Cir. 2003), the Court noted that an agreement that transferred rights to use a computer program—styled as a 'lease'—which included both the program itself and a warranty of usability did not avoid the on-sale bar. In contrast, the Agreement at issue here is plainly intended to transfer a research and development project, with associated patent rights and know-how, rather than a transfer of the invention itself. Thus it is much more factually analogous to cases such as *Mas-Hamilton*, *Kollar* and *Micro-Magnetic Industries* than to simple transfers of the invention such as the purchase orders in *Pfaff* or the software lease at issue in *Minton*. Thus, I believe my analysis above—that the Agreement does not trigger the on-sale bar—is fully supported by current Federal Circuit law.

35. Indeed, I believe that a holding that the Agreement here was a commercial sale or offer for sale under 35 § U.S.C. § 102(b) would be a troubling extension of the law—undermining the principle from *Pfaff* that the invention must be actually commercialized in order to trigger the on sale bar. Allowing agreements whose purpose was to transfer research efforts to trigger the on-sale bar would create strong disincentives for such transfers—the loss of potential patent rights could undermine the entire purpose of the transaction. In addition, such a holding would call into question whether corporate mergers or sales, the formation of joint ventures, or other types of transactions not directly intended to commercialize inventions could nonetheless trigger the on-sale bar (and thus preclude important patent rights) by virtue of the transfer of assets that occurs in such circumstances. Indeed, in *Pfaff*, the Supreme Court noted that the on-sale bar (like all of patent law) involves a careful balance: "The patent laws therefore seek both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention." *Pfaff v. Wells Electronics, Inc.,* 525 U.S. 55, 65 (1998).

36. In my opinion, the Agreement between Syntex and CVT is not a commercialization of the inventions at issue, and thus does not trigger the prohibitions of 35 U.S.C. § 102(b).

C. Any Sales of the Invention as part of the Agreement are Primarily Intended for Experimentation and thus do not Trigger the On-Sale Bar.

37. Even if the Agreement is understood to be a commercialization of the inventions at issue under 35 U.S.C. § 102(b), the purpose of the transfer of the materials as part of the Agreement is primarily for purposes of experimentation, and thus does not trigger the on-sale bar. As the Supreme Court noted in *Pfaff*, "an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention—even if such testing occurs in the public eye. The law has long recognized the distinction between inventions put to experimental use and products sold commercially." *See* 525 U.S. 55, 64, (1998). *See also Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126, 137 (1877). Thus, as the Federal Circuit has held, any consideration of whether a transaction triggers the on-sale bar must "involve[] an assessment of whether the circumstances surrounding the transaction show that the transaction was not primarily for purposes of experimentation." *Allen Eng'g Corp. v. Bartell Indus., Inc.,* 299 F.3d 1336, 1352-53 (Fed. Cir. 2002).

[redacted]

39. Milestones associated with the Agreement [redacted]

40. My analysis of the experimental nature of the transactions established by the Agreement is confirmed by the testimony of a named inventor to the relevant patents himself, Dr. Andrew Wolff, who has testified that [redacted]

41. [redacted]

See also In re Omeprazole Patent Litig

to pharmaceutical formulation were not reduced to practice prior to Phase III clinical trials because the inventors did not know the invention would work for its intended purpose).

42. Under the law, these facts — [redacted] preclude the application of

entor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent

for his invention—even if such testing occurs in the public eye. The law has long recognized the distinction between inventions put to experimental use and products sold commercially. Experimentation evidence includes tests needed to convince [the inventor] that the invention is capable of performing its intended purpose in its intended environment." *EZ Dock v. Schafer Sys., Inc.*, 276 F.3d 1347, 1352 (Fed. Cir. 2002) (citations and quotations omitted).

43. Further, the Federal Circuit has held that until an invention is reduced to practice, "up to that point, regardless of the stage of development of the invention, and quite apart from the possible satisfaction of the second prong of the *Pfaff* test, the inventor is free to experiment, test, and otherwise engage in activities to determine if the invention is suitable for its intended purpose and thus satisfactorily complete." *Allen Eng'g Corp. v. Bartell Indus., Inc.,* 299 F.3d 1336, 1354 (Fed. Cir. 2002) (quoting *EZ Dock*, 276 F.3d at 1356-57 (Linn, J., concurring)).

44. [redacted]

III

CONCLUSION

45. For the reasons stated above, I believe that the Agreement dated March 27, 1996 between Syntex (USA) Inc., and CV Therapeutics Inc. does not create an on-sale bar under 35 U.S.C. § 102(b) for the patents at issue in this litigation.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: November 9, 2012

R. Polk Wagner, J.D.

Exhibit A

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Fall 2011, Fall 2010, Fall 2009, Spring 2009

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AY, 2011-12, AY 2010-11, AY 2009-10, AY 2007-08, AY 2006-07, AY 2005-06, AY 2004-05, AY 2002-03

ELECTRONIC COMMERCE
Fall 2001, Fall 2000

ADVANCED PATENT LAW (SEMINAR)
Fall 2006

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Spring 2002

INSTITUTIONAL SERVICE

FACULTY APPOINTMENTS COMMITTEE
Chair (Entry & Lateral): 2009-10, Chair (Entry-Level): 2007-08, Member: 2005-06

BUILDING COMMITTEE
Chair: 2011-12; Chair: 2010-11; Member: 2009-2010

EDUCATIONAL PROGRAMS COMMITTEE
Member: 2009

CURRICULAR REFORM COMMITTEE
Member: 2009

ADMISSIONS COMMITTEE
Chair, 2006-07; Member: 2002-03, 2001-02

TECHNOLOGY COMMITTEE
Member: 2010-11, 2006-07, 2004-05, 2003-04, 2001-02, 2000-01

SEARCH COMMITTEE FOR DEAN OF ADMISSIONS
2006-07, 2002-03

CONFLICT OF INTEREST STANDING COMMITTEE (CISC) *(University-Wide)*
Vice-Chair: 2008–; Member: 2002–

CENTER FOR TECHNOLOGY TRANSFER GOVERNING BOARD *(University-Wide)*
Member: 2006–

PROVOST'S COUNCIL ON RESEARCH *(University-Wide)*
Member: 2010-11, 2009-10, 2008-09; 2007-08, 2006-07, 2005-06, 2004-05

LEVY SCHOLARS PROGRAM
Advisor: 2003-04

UNIVERSITY COMMUNICATIONS COMMITTEE *(University-Wide)*
Member: 2003-04, 2002-03

AD HOC SEMINAR SERIES
Organizer: Summer 2004, 2003-2004 (with D. Skeel), 2002-03, Summer 2002 (with M. Knoll)

WILSON FELLOWS IN HIGH-TECHNOLOGY
Advisor/Organizer: 2002-03 *(Weekly seminars & advisory functions)*

PHILADELPHIA AREA 'CYBERLUNCH' DISCUSSION GROUP
Organizer: 2004-05, 2003-04, 2002-03, 2001-02

UNIVERSITY OF PENNSYLVANIA CENTER FOR TECHNOLOGY TRANSFER
Board of Advisors: 2004-05, 2003-04, 2002-03, 2001-02

INSTITUTE FOR STRATEGIC THREAT AND RESPONSE (ISTAR) *(Penn institute)*
Affiliate: 2003-04, 2002-03, 2001-02

INSTITUTE FOR LAW & ECONOMICS WORKSHOP SERIES
Organizer: 2001-02 (with M. Knoll)

SEARCH COMMITTEE FOR DIRECTOR OF INFORMATION TECHNOLOGY
2000-01

PENN INTELLECTUAL PROPERTY INTEREST GROUP
Advisor: 2007-08, 2004-05, 2003-04, 2002-03, 2001-02

OTHER EMPLOYMENT

HONORABLE RAYMOND C. CLEVENGER, III
U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT
LAW CLERK, 1998 – 2000

WEIL, GOTSHAL & MANGES, LLP — SILICON VALLEY OFFICE
SUMMER ASSOCIATE, MAY – AUGUST 1997

D'ALESSANDRO & RITCHIE, LLP
SUMMER ASSOCIATE, MAY – AUGUST 1996

DIVISION OF STUDENT AFFAIRS, UNIVERSITY OF MICHIGAN
POLICY DEVELOPMENT, SPRING 1994

MARINE HYDRODYNAMICS LAB, UNIVERSITY OF MICHIGAN
STUDENT RESEARCHER, SUMMER 1993

PROFESSIONAL MEMBERSHIPS

ADMITTED TO PRACTICE IN THE STATE OF CALIFORNIA
ADMITTED TO PRACTICE BEFORE THE U.S. PATENT AND TRADEMARK OFFICE
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UNITED STATES SAILING ASSOCIATION

EXHIBITS B-D TO

DECLARATION OF R. POLK WAGNER, J.D.

REDACTED IN THEIR ENTIRETY